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Filed : February 1, 2002

### REMARKS

Claims 1-19 were pending in the application. Pursuant to the above claim amendments, Claims 1, 4, 5, 7, 13, 15 and 19 have been amended. Finally, Applicant has added new claims 20-27.

#### Claim Rejections – 35 U.S.C. § 102

Claims 1-3, 5-8, 13-17 and 19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wagner. The Examiner alleges that Wagner discloses the invention substantially as claimed. Applicant respectfully disagrees with the Examiner's statement

Wagner discloses forceps for nuclear fragment removal. The forceps "are formed of a pair of elongated arms at the tips of which tiny hemispherical or oval cup-shaped implements are mounted." *See* abstract. "The perimeters of the implements from [sic] cutting edges that are capable of being brought into mutual contact throughout to entrap loose nuclear fragments therebetween." *Id.* "[T]he implements 52 and 54 can be clamped together by the fingers of the eye surgeon performing the operation by pressing on the portions of the lever arms 42 and 44 relatively near the fulcrum 46." Col. 5, lines 33-36. Thus, the lever arms are biased away from each other and require an external, manual force to bring them together. When the lever arms are brought together, "the cutting edges 60 and 62 cleanly and sharply sever the contents within the enclosure formed between the implements 52 and 54 from the surrounding material." *Id.*, at lines 26-30. Subsequently, "[t]he forceps 40 are then drawn away from the eye of the patient while the cup-shaped implements 52 and 54 remain pressed together so as to extract the entrapped nuclear fragment 20 from the patient's eye." *Id.*, at lines 40-44. In order to entrap and extract the nuclear fragment, the forceps of Wagner are configured with "tiny hemispherical or oval cup-shaped implements." *See* Abstract.

#### Claims 1-3 and 5-8

In contrast to the forceps of Wagner, Claim 1 recites, *inter alia*, a device for isolating deleterious body tissue located within healthy body tissue from the healthy body tissue by limiting blood and fluid communication with the deleterious body tissue, the device having first and second circumferential surfaces wherein the "first and second circumferential surfaces co-act to isolate the deleterious body tissue from communication with the healthy body tissue; wherein the device is configured to maintain the first and second structures together in an aligned relationship." Such a structure is not taught or suggested by Wagner. Among other things,

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Wagner does not teach a device “configured to maintain the first and second structures together in an aligned relationship.” As discussed above, Wagner require an external, manual force to press the forceps together. Accordingly, Applicant believes Claim 1 recites subject matter patentable over Wagner, and Applicant requests allowance of Claim 1.

In addition, the Claims that depend from Claim 1 each recite a unique combination of features not taught or suggested by Wagner. For example, Claim 2 recites, *inter alia*, “a bias element coupled to the first structure and the second structure that brings the circumferential surfaces of the first and second structures together in an aligned relationship.” Wagner does not teach or suggest such a device. Accordingly, Applicant requests allowance of Claims 1-12.

#### Claims 13-14

Claim 13 has been voluntarily amended to provide proper antecedent support by clarifying the first and second circumferential surfaces recited in the claim are the same first and second partial circumferential surfaces introduced earlier in the claim, and does not narrow the scope of the claim.

In contrast to the teachings of Wagner, Independent Claim 13 recites, *inter alia*, “a first structure, including a first partial circumferential surface; and a second structure, including a second partial circumferential surface corresponding to the first partial circumferential surface.” As discussed above, Wagner is configured with hemispherical or oval cup-shaped implements configured to entrap and remove nuclear fragments. As such, Wagner does not teach or suggest the device of Claim 13. Applicant thus requests allowance of Claim 13.

In addition, Claim 14 recites, *inter alia*, “a bias element coupled to the first structure and the second structure that brings the circumferential surfaces of the first and second structures toward each other with sufficient force such that deleterious body tissue enclosed therein becomes ischemic and necrotic.” Such a structure is not disclosed by Wagner. As such, Applicant requests allowance of Claim 14.

#### Claims 15-17

Wagner teaches a device having cutting edges that cleanly and sharply sever the contents within the implements to entrap and extract nuclear fragments. In contrast to the teachings of Wagner, amended Claim 15 recites, *inter alia*, a method of isolating deleterious body tissue comprising the step of “bringing the first and second circumferential surfaces of the device together in an aligned relationship with the deleterious body tissue between the first and second

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structures, wherein the first and second circumferential surfaces co-act to isolate the deleterious body tissue from communication with the healthy body tissue without severing the deleterious body tissue from the healthy body tissue.” Thus, Claim 15 is not anticipated by Wagner, and Applicant requests allowance of Claim 15.

In addition, Claims 16 and 17, which depend from Claim 15 each recite a unique combination not taught by Wagner. Accordingly, Applicant requests allowance of Claims 16 and 17 in addition to Claim 15.

#### Claim 19

As discussed above, Wagner teaches a forceps having implements that can be brought together by the fingers of the eye surgeon performing the operation by pressing on the portions of the lever arms near the fulcrum. In contrast to this teaching, Claim 19 recites, *inter alia*, “means for maintaining the circumferential surfaces together with sufficient force that deleterious body tissue confined therein will be isolated from communication with healthy body tissue.” Such a structure is not taught or disclosed by Wagner, and as such, Applicants kindly request allowance of Claim 19:

#### **Claim Rejections - 35 U.S.C. § 103**

##### Claims 4 and 18

Claims 4 and 18 stand rejected under 35 U.D.C. § 103(a) as being unpatentable over Wagner in view of Domino. The Examiner alleges that Wagner discloses the invention as claimed except for the first and second apertures. Applicant respectfully submits that Wagner does not disclose the invention as claimed for the reasons stated above. The Examiner then cites Domino for the teaching of a surgical device having apertures and then concludes that “it would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify the structure of Wagner’s device by providing a central aperture to the first structure 52 and second structure 54 for allowing access to the deleterious body tissue for excision.”

Respectfully, rather than make broad conclusory statements, the Examiner is required to provide more concrete evidence in order to establish a *prima facie* case of obviousness. See *In re Dembiczak*, 175 F.3d 994, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999); see also *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992). Specifically, the Examiner is required to make particular findings regarding the locus of the suggestion, teaching, or motivation to combine the prior art references. *Dembiczak*, 175 F.3d 994, 50 U.S.P.Q.2d at 1617. The Federal Circuit has

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stated that the “suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.” In re *Rouffet*, 149 F.3d 1350, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). The Court continued by explaining its rationale: “If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention.” *Id.* The Examiner has not established a prima facie case of obviousness by making “particular findings regarding the locus of the suggestion, teaching or motivation to combine the prior art references.” *Dembiczak*, 175 F.3d 994, 50 U.S.P.Q.2d 1614. Consequently, the suggested combination of Wagner and Domino is improper.

In addition to a lack of motivation to combine the references, the references themselves teach away from such a combination. Specifically, Wagner is aimed at providing forceps for severing and removing nuclear fragments of a lens of an eye during eye surgery. As such, the forceps are configured with lever arms each having tiny hemispherical or oval cup-shaped implements configured with cutting edges that are capable of being brought into mutual contact throughout to entrap loose nuclear fragments therebetween. At Column 5, lines 19-30, Wagner specifically teaches that the implements create an enclosure. “The forceps 40 are then drawn away from the eye of the patient while the cup-shaped implements 52 and 54 remain pressed together so as to extract the entrapped nuclear fragment 20 from the patient’s eye.” *Id.* Adding the apertures of Domino to the forceps of Wagner would obviate the purpose of Wagner, which is to extract the entrapped nuclear fragment from a patient’s eye. Adding apertures to the implements would provide a means of escape for the nuclear fragments rather than causing them to be entrapped, thus negating the purpose of Wagner’s device. Wagner thus teaches away from combining the apertures of Domino with the device of Wagner.

Thus, Applicant submits that there is no motivation to combine the references, and in fact, Wagner teaches away from such a combination. Accordingly, Applicant requests allowance of Claims 14 and 18.

#### Claims 9-12

Claims 9-12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wagner in view of Green. The Examiner alleges that Wagner discloses the invention as claimed except

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for a first interlocking surface and a second interlocking surface. Applicant disagrees with the Examiner's assertion for the reasons stated above.

Furthermore, Applicant believes that Wagner teaches against the combination suggested by the Examiner. Wagner discloses forceps having cup-shaped implements with one implement formed with a blade edge while the other implement is formed with a V-shaped indentation adapted to receive the blade edge of the cutting edge. "In this way when the implements 52 and 54 are brought together, the cutting edges 60 and 62 cleanly and sharply sever the contents within the enclosure formed between the implements 52 and 54 from the surrounding material." Col. 5, lines 23-26. This is accomplished by forceps configured with lever arms each having tiny hemispherical or oval cup-shaped implements configured with cutting edges that are capable of being brought into mutual contact throughout to entrap loose nuclear fragments therebetween. The forceps are then drawn away from the eye of the patient while the cup-shaped implements 52 and 54 remain pressed together so as to extract the entrapped nuclear fragment 20 from the patient's eye. In order to achieve this goal, the cup-shaped implements are configured with cutting edges to "cleanly and sharply sever the contents within the enclosure."

If the interlocking surfaces of Green were added to the forceps of Wagner, such a result would not allow the contents to be "cleanly and sharply severed" and extracted because the interlocking structure of Green does not provide cutting edges. Thus, Applicant submits that Green does not teach the combination. For these reasons, Applicant submits that Claim 9 recites unique subject matter not taught or suggested by the cited references, either alone or in combination, and therefore requests allowance of claim 9. In addition, Claims 10-12 each recite a unique combination of features not taught or suggested by the prior art references, and thus are also in condition for allowance.

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### CONCLUSION

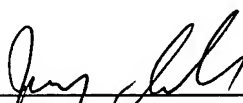
Applicant has amended Claims 1, 4, 5, 7, 13, 15 and 19. In addition, Applicant has added Claims 20-27. Accordingly, Claims 1-27 are pending for consideration. Applicant submits that each claim recites subject matter that is patentable over the cited references, and Applicant respectfully requests allowance of the same.

Applicant has endeavored to respond to each of the issues raised by the Examiner. However, if there remain any unresolved issues that could be resolved via a telephone conference, Applicant invites the Examiner to initiate the same with Applicant's representative at the telephone number shown below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 22 March 2004

By:   
Jeremy P. Sanders  
Registration No. 47,916  
Attorney of Record  
Customer No. 20,995  
(949) 760-0404

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